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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,950	09/26/2001	Gavriel Meron	P-3571-US	9876

27130 7590 04/08/2004

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

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DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,950

Applicant(s)

MERON ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-15, 17-19, 21, 23-28, 31-40, 47, 48, 50, 51, 53-58, 60, 63-65, 67, and 68 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-15, 17-19, 21, 23-28, 31-40, 47, 48, 50, 51, 53-58, 60, 63-65, 67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 41-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Before beginning the office action, the examiner wishes to note that applicant has defined the phrase "configured to be immobilized" to mean that the device has structure allowing it to be immobilized, as opposed to merely being capable of being immobilized.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no disclosure of a device having a housing containing an imaging device and a sensing device, where the sensing device measures electrical conductivity of tissue. Since this limitation was added via amendment, it constitutes new matter. Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 38, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 is rejected in that claim 23 recites

an in vivo imaging device. Claim 25 recites a further element that receives data from the imaging device. It is unclear an element of the imaging device receives data from the imaging device. Claims 38 and 40 are rejected for being duplicates of each other.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 26, 27, 32, 33, 34, 38-40, 47, 48, 50, 51, 55-58, 60, 67, and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Swain et al WO 98/11816. The examiner notes that the limitations agreed to define over Swain were not added to claims 23, 47, or 63. Swain et al has an implantable image sensor including an imaging sensor (44, 46, and 48), a battery 52 or an externally engageable power source (see column 6) and a wireless transmitter 54. It further notes in column 6, lines 18-24 that it has a loop for sewing it into the tissue to immobilize the capsule 42 and 40. With respect to claims 18 and 38, the anchoring means is the thread. Swain further has an external receiver and display for displaying the image data. The examiner notes that immobilizing the device requires some surgical procedure and hence the immobilization occurs during surgery.

Claims 1, 2, 4, 11, 12, 17-19, 21, 23, 24, 32, 33, 38, 39, 40, 47, 48, 50, 51, 53, 54, 55, 56, 57, 58, 60, 63-65, are rejected under 35 U.S.C. 102(b) as being anticipated by Doi JP 5015515. Doi shows a capsule having an imaging device for imaging the GI

tract with clips for clipping the device to the digestive lining to immobilize the device. Data is sent via a transmitter to an external receiver, which displays the images on a monitor. Doi also teaches the method of monitoring recited in the claims.

Claims 23, 24, 26, 27, 32-35, 38-40, 47, 48, 50, 51, 53-54 and 63-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Kilcoyne et al. The examiner notes that claim 23 recites in the preamble an imaging device. However, the claim does not state that the device takes an image. The examiner notes that, as will be discussed, Kilcoyne shows the recited structure.

Kilcoyne shows an implantable housing 18, including a sensor 110 which can be any known in vivo biomedical sensor, a rf transmitter 112 for transmitting data to an external receiver and monitor, and a battery 114. The examiner notes that Kilcoyne is not an imaging device in that it does not have a camera that provides an optical reproduction of the measurement site. However, nothing in the claim body purports to limit the claim to such a degree. The claim merely requires an in vivo sensor, which is present in Kilcoyne. Applicant might overcome this rejection by reciting that the sensor is an imaging sensor. The device is immobilized in place using a thread through loop 112, or other attachment means (see column 7, lines 34-45). Kilcoyne further teaches the recited method. With respect to claims 63-65, the examiner notes that the immobilizing step is surgery.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-7, 11-15, 17-19, 23, 24, 26, 27, 28, 32-40, 47, 48, 50, 51, 53-58, 60, and 63-65 are rejected under 35 U.S.C. 103(a) as being obvious over Marshall in view of Swain et al WO 98/11816. Marshall shows a swallowable capsule include two sensors, one of which can be an image sensor and one a pH sensor and a wireless transmitter 62, for transmitting the data to an external receiver. Marshall further includes a battery 58 inside the capsule. The examiner notes that the capsule of Marshall et al images the digestive tract as it moves through the system. Swain et al shows a device for the identical purpose as Marshall which teaches that in some applications it is also desirable to provide a loop to allow the device to be sewn in place and immobilized for monitoring. Hence, it would have been obvious to modify Marshall et al to use such a loop and immobilization technique, as it is merely the substitution of one known equivalent monitoring technique for another. With respect to claims 14, 15, 36, and 37, the combination does not have the same structure recited in these claims. The examiner notes that the exact structure for engaging the sutures does not solve a stated purpose and is not for a specific reason. As such, the exact structure would have been a mere matter of obvious design choice for one skilled in the art. With respect to claims 60, 63-65, the examiner notes that the step of immobilizing the device is surgery and hence the monitoring occurs after surgery.

Claims 3 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Swain, as applied to claims 1, 2, 4-7, 11-15, 17-19, 23, 24, 26, 27, 28, 32-40, 47, 48, 50, 51, 53-58, 60, and 63-65 above, further in view of in view of

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Sohrab. Sohrab shows an analyte monitoring device that varies the frequency of measurement based on the analyte levels measured, to avoid unnecessary measurements. . Hence, it would have been obvious to modify Marshall et al to vary to measurement frequency based on the measured data (i.e. there would be a controller that controls the measurement), to use the device as efficiently as possible.

Claims 5, 6, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Iddan et al. Iddan et al further teaches the use of an externally rechargeable battery in the implantable device, such as that of Doi, to extend the useable life of the device. Hence, it would have been obvious to modify use an externally chargeable battery in Doi, to extend its useable life.

Claims 10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Swain, as applied to claims 1, 2, 4-7, 11-15, 17-19, 23, 24, 26, 27, 28, 32-40, 47, 48, 50, 51, 53-58, 60, and 63-65 above, further in view of in view of Fiddian –Green. Fiddian-Green shows a pH sensor whose optical characteristic change in response to pH. It would have been obvious to modify the above combination to use such a sensor, as it is merely the substitution of one known pH sensor for another.

Claims 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swain et al et al. Swain et al shows a device that is sewn into the digestive tract. It does not have the same structure recited in these claims. The examiner notes that the exact structure for engaging the sutures does not solve a stated purpose and is not for a specific reason. As such, the exact structure would have been a mere matter of obvious design choice for one skilled in the art.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Sohrab. Sohrab shows an analyte monitoring device that varies the frequency of measurement based on the analyte levels measured, to avoid unnecessary measurements. . Hence, it would have been obvious to modify Kilcoyne et al to vary to measurement frequency based on the measured data (i.e. there would be a controller that controls the measurement), to use the device as efficiently as possible.

Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Swain et al. With respect to claim 67 and 68, Swain et al teaches the equivalence of a battery and an external engageable power source. Hence, it would have been obvious to modify Kilcoyne to use an externally engageable power source, as it is merely the substitution of one known equivalent sensor for another.

Claims 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Fiddian –Green. Fiddian-Green shows a pH sensor whose optical characteristic change in response to pH. It would have been obvious to modify Kilcoyne et al to use such a sensor, as it is merely the substitution of one known pH sensor for another.

Claims 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al. Kilcoyne et al shows a device that is sewn into the digestive tract. It does not have the same structure recited in these claims. The examiner notes that the exact structure for engaging the sutures does not solve a stated purpose and is not

for a specific reason. As such, the exact structure would have been a mere matter of obvious design choice for one skilled in the art.

Claims 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swain et al et al. Swain et al shows a device that is sewn into the digestive tract. It does not have the same structure recited in these claims. The examiner notes that the exact structure for engaging the sutures does not solve a stated purpose and is not for a specific reason. As such, the exact structure would have been a mere matter of obvious design choice for one skilled in the art.

Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Iddan et al. Iddan et al further teaches the use of an externally rechargeable battery in the implantable device, such as that of Marshall, to extend the useable life of the device. Hence, it would have been obvious to modify use an externally chargeable battery in Marshall, to extend its useable life.

Applicant's arguments filed 1/13/2004 have been considered, but are not considered to be persuasive.

Applicant notes that during the interview, it was agreed that the amendments overcame the rejections of record. The examiner notes that claim 1 was amended as discussed, but claims 23, 47, and 63 were not. As such, only a portion of the rejections of record have been dropped.

The remainder of applicant's arguments have been deemed moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
April 4, 2004

Robert L. Nasser
ROBERT L. NASSER
PRIMARY EXAMINER